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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/084,441 05/27/98 LIN

J 62-575

020736

QM12/1008

EXAMINER

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WASHINGTON DC 20036-3307

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3739

DATE MAILED:

10/08/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

U.S. GOVERNMENT PRINTING OFFICE: 1995 500-100-016

## Office Action Summary

Application No.  
09/084,441

Applicant

Lin

Examiner

Michael Peffley

Group Art Unit

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- Responsive to communication(s) filed on May 5, 1999
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

- Claim(s) 1-106 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) 1-106 is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \*Certified copies not received: \_\_\_\_\_
- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). 5
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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***Preliminary Amendments***

Applicant is hereby notified that the preliminary amendments filed May 27, 1998 and May 5, 1999 are not in accordance with 37 CFR 1.121 and MPEP 1453. In particular, the addition of new claims must be underlined. Therefore, new claims 105 and 106 added with the amendment of May 5, 1999 must be underlined in their entirety. Moreover, subsequent amendments to newly added claims must also be underlined in their entirety. As such, the amendment of May 27, 1998 changing the dependency of claims 100-104, and the amendment of May 5, 1999 are both improper under the rules. In the interest of expediting prosecution, these claims have been examined as though the amendments were entered. However, applicant is required to file corrective amendments for the May 27, 1998 and May 5, 1999 filings. Further amendments to the claims should also be made in accordance with the rules for making amendments in reissue applications (see MPEP 1453).

Also, it is noted that applicant's May 5, 1999 amendment makes reference to a protest filed in the application. No such protest was found in the application papers as of the time of the examination by the examiner. If protest papers are properly filed in the application at a later date, those papers will be reviewed accordingly.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-38, 42, 50, 51, 59, 61, 62, 77 and 86 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims recite a repetition rate of at least 20 hertz. While there is support in the specification for various ranges of repetition rate, there is no specific disclosure that the repetition rate should specifically be at least 20 hertz. Rather, the specification does indicate that the repetition rate should be at least 50 hertz.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims set forth an energy range which is not within the range set forth in claim 1. In particular, claim 1 recites an energy level which is less than 10 millijoules. This limitation does not include 10 millijoules in the range. However, claims 3 and 4 both recite an energy level which includes 10 millijoules in the range. These claims are therefore indefinite since they are not within the range set in claim 1. Similarly, claims 8-10 recite energy ranges which are beyond the "less than 10 millijoules" range set forth in claim 1 making the claims indefinite.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 69, 70, 73-75 and 99-103 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Lin ('630).

The patent to Lin discloses several laser sources (UV and IR) which are used for ophthalmic procedures. In particular, the lasers include a pulsed laser having a repetition rate of at least 50 hertz, and a scanner means to deliver the laser energy to tissue. Numerous types of laser sources are disclosed (including excimer) in various UV and IR wavelengths. The method of

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using the device (i.e. applying energy to the cornea) is inherent to the structure and disclosure of the Lin device.

In general, the Lin disclosure teaches that it is known to provide smaller (i.e. low power) lasers with a high repetition rate and small beam diameter to treat corneal tissue (column 7).

Claims 24-47, 69-80, 82-86, 89-98 and 106 are rejected under 35 U.S.C. 102(a) as being anticipated by Lai (PCT/US92/09625).

Lai disclose a laser system for treating corneal tissue. The laser is a UV laser which is operated at low energy levels of less than 10 millijoules with a repetition rate up to 10 kHz. The laser is in the 193-300 nm wavelength range, and the beam cross section is 1 mm or less (see page 13). The beam is used to remove tissue to a depth of 0.05-0.2 microns per pulse (page 27), and the beam may be scanned across tissue in numerous patterns. The scanning is performed with the aid of a computer, and the pattern may be linear, concentric circles, and overlapping. The structure for performing the surgery is disclosed, as are the method steps of using the apparatus to treat corneal tissue. Lai also discloses the use of an He-Ne aiming laser (132) used during surgery.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 11-23, 48-68, 81, 87, 88 and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai (PCT '625) in view of the teaching of Bille et al ('718).

The Lai device and method of use has been addressed previously. While Lai teaches the use of a computer to control the scanning of the laser beam, there is no specific teaching of the use of a galvanometer scanner to scan the beam to corneal tissue.

The examiner maintains that there are several known means for scanning a laser beam onto tissue. Among these several well known means is a galvanometer scanner. Bille et al disclose such a laser beam scanner means. The Bille et al system includes a laser to treat corneal tissue, and a galvanometric scanner for locating the laser beam at various desired locations. The Bille et al galvanometric mirrors are provided with coatings for focusing specific wavelengths.

To have provided the Lai system with a galvanometric scanner to scan the laser beam onto corneal tissue would have been an obvious modification for one of ordinary skill in the art, particularly since Bille et al teach that it is known to use such a galvanometric scanner to scan laser light onto corneal tissue.

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Claims 2 and 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai ('625) and Bille et al ('718) as applied to the claims in the immediately previous rejection above, and further in view of the teaching of Lin ('630).

The combination of the Lai system with the Bille et al galvanometric scanner system has been addressed. Lai only teaches of the use of UV lasers for the corneal eye surgery, and fail to disclose the use of IR lasers for the same procedure.

Lin, as discussed previously, teach that it is known to use both UV and IR lasers for corneal surgery. Moreover, Lin teach that the purpose of the invention is to provide either UV or IR lasers with low power and with high repetition rates and small beams to treat corneal tissue (column 7).

To have provided an IR laser in the Lai system, as modified by the teaching of Bille et al, would have been an obvious substitution for one of ordinary skill in the art, particularly since Lin teaches that it is known to use both UV and IR lasers in low power settings for the treatment of corneal tissue.

Claims 99-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai ('625) in view of the teaching of Lin ('630).

The Lai system has been previously addressed. Lai fails to disclose the use of IR lasers for the treatment of corneal tissue using the low energy, high repetition rate and small beam system. Rather, Lai only discloses the use of UV lasers for the corneal surgery procedures.

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Lin teaches that both UV and IR lasers are known for use in treating corneal tissue. Moreover, Lin teaches that the lasers may be provided with low energy, high repetition rate and small beam size (column 7) for the treatment of corneal tissue.

To have substituted an IR laser system in the Lai system for the treatment of corneal tissue would have been an obvious modification for one of ordinary skill in the art, particularly since Lin teaches that both UV and IR lasers are known to be used for treating corneal tissue.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Simon et al ('396) and Hanna et al ('477) disclose various scanning mechanisms for use with laser eye surgical systems.

Marshall et al ('093) discloses the use of low power lasers for the treatment of corneal tissue. Energy levels as low as 5 millijoules per pulse are disclosed (column 7, lines 33-38).

Seiler ('190) also discloses the use of low energy lasers for treating corneal tissue. Energies as low as 8-10 millijoules per pulse are disclosed (column 6, lines 14-19).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm.

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In the event the examiner can not be reached or is absent from the Office, the examiner's supervisor, Linda Dvorak, can be reached at (703) 308-0994.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858. The formal fax number for the Group is (703) 305-3590.

Michael Peffley/mp  
Primary Examiner  
Art Unit 3739  
September 30, 1999

*Michael Peffley*  
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PRIMARY EXAMINER  
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